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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0557]

"Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans.'' The guidance document is being issued in response to public comments and recent interest among clinical investigators in using nonhuman primate xenografts in the near future. The document is intended to provide guidance on nonhuman primate xenotransplantation in humans.

DATES: Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the* **Federal Register**), to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues, and organs from nonhuman primate xenografts in humans.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that

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office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans.'' The document provides guidance to industry concerning: (1) The potential public health risks posed by nonhuman primate xenografts; (2) the need for further scientific research and evaluation of these risks, particularly infectious agents; and (3) the need for public discussion concerning these issues.

Concerns have arisen in the last few years about the potential infectious disease and public health risks associated with xenotransplantation, particularly nonhuman primate xenotransplantation. For the purpose of this guidance document, xenotransplantation is defined as any procedure that involves the use of live cells, tissues, or organs from a nonhuman animal source transplanted or implanted into a human, or used for ex vivo contact with human body fluids, cells, tissues, or organs that are subsequently given to a human recipient. In addition, defined for the purpose of this document, xenografts include live cells, tissues, or organs from a nonhuman animal source used for xenotransplantation.

In developing the guidance, FDA considered numerous sources of information, including concerns raised in public comments to the ''Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation'' (61 FR 49920, September 23, 1996) and concerns voiced by the scientific and lay community at the public workshops on xenotransplantation entitled ''Cross–Species Infectivity and Pathogenesis'' held on July 21 and 22, 1997, and ''Developing U.S. Public Health Service Policy in Xenotransplantation'' held on January 21 and 22, 1998, sponsored by PHS.

The approach outlined in the guidance document has been accepted by the other PHS agencies including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, as well as the Department of Health and Human Services Working Group on Xenotransplantation. The agency is aware that other species of animals have been used and are proposed as future sources of xenografts and may pose infectious disease risks. The public health issues raised by xenotransplantation, regardless of source animal species, will continue to receive scientific evaluation and discussion by appropriate Federal agencies and advisory committees.

The guidance document represents the agency's current thinking on the potential public health risks posed by the use of nonhuman primate xenografts in humans, and the consequent need for further scientific evaluation and public discussion of this issue. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The agency notes that measures taken during the production of some nonhuman primate xenografts products, such as extensive preclinical xenotransplant product testing for infectious

agents, genetic engineering, enclosure of the product in a semipermeable barrier, and/or the use of well-characterized cell lines which have been handled in a manner to avoid the introduction of new pathogens, could potentially provide greater control of infectious disease risks. The agency specifically solicits comments on the potential for such measures, alone or in combination, to substantially reduce the risks posed by nonhuman primate xenotransplantation. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues and organs from nonhuman primate xenografts in humans.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the* **Federal Register**), to ensure adequate consideration in preparation of a revised document, if warranted. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: March 30, 1999

William K. Hubbard
Acting Deputy Commissioner for
Policy

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